

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK**

CANDACE JOHNSON)
)
 PLAINTIFF,) C.A. No. 5:18-CV-1156 [GLS/DEP]
)
 v.)
)
 C.R. BARD, INC. and DAVOL, INC.,)
)
 DEFENDANTS.)

COMPLAINT AND JURY DEMAND

The Plaintiff, Candace Johnson, by and through the undersigned counsel, hereby files this Complaint against the Defendants, C.R. Bard, Inc. and Davol, Inc., in this litigation and states as follows:

JURISDICTIONAL STATEMENT

1. This Court has jurisdiction over the subject matter of the within action pursuant to 28 U.S.C. §1332 as the action is between citizens of different states and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

PARTIES

2. At all times material Plaintiff Candace Johnson was a resident of Onondaga County, New York.
3. Defendant C.R. Bard, Inc. is a New Jersey Corporation with its principal place of business in New Jersey.

4. Defendant C.R. Bard, Inc. has substantial contacts with Onondaga County, New York, which are more than sufficient to cause them to be subject to personal jurisdiction in said county.
5. Defendant Davol, Inc. is a Rhode Island Corporation with a principal place of business in Rhode Island.
6. Defendant Davol, Inc. has substantial contacts with Onondaga County, New York, which are more than sufficient to cause them to be subject to personal jurisdiction in said county.
7. Defendant Davol, Inc. is a subsidiary of Defendant C.R. Bard, Inc.
8. A substantial part of the events and omissions giving rise to Plaintiff's claim occurred in Onondaga County, New York, such that venue is proper.
9. The Plaintiff underwent an operation on or about May 5, 2014, by Dr. James Sartori in Syracuse, New York, to repair a hernia, during which operation a variety of surgical mesh manufactured, sold and marketed by Defendants C.R. Bard and Davol was implanted.
10. The surgical mesh used in the surgery was known as the "Ventralex Hernia Patch" (herein referred to as "Product") and it was designed, manufactured, packaged, labeled, marketed, sold, and distributed by Defendants C.R. Bard and Davol.
11. The Product was made of materials that are biologically incompatible with human tissue and react negatively and sometimes dangerously with a large number of those on whom it is used.

12. Defendants C.R. Bard and Davol knew or should have known that their Product was unreasonably harmful.
13. The scientific evidence demonstrates that the mesh is incompatible with human tissue and often causes a negative immune response in patients implanted with the Product, including Plaintiff.
14. Defendants C.R. Bard and Davol knew or should have known of this evidence.
15. Ventralex is marketed to the medical community and to patients as a safe, effective, and reliable medical device, implanted by safe and effective, minimally invasive surgical techniques, and is marketed as safer and more effective as compared to other products.
16. Defendants C.R. Bard and Davol failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Product.
17. Feasible and suitable alternatives to the Product have existed at all times relevant that do not present the same frequency or severity of risks as the Product.
18. The Product was at all times utilized and implanted in a manner foreseeable to and in fact intended by Defendants C.R. Bard and Davol, its instructions and procedures for use and its training of the health care providers.
19. The Product was implanted in Plaintiff in the same or substantially similar condition as when it left the possession of Defendants C.R. Bard and Davol.
20. Defendants C.R. Bard and Davol failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Product.
21. The Product as designed, manufactured, distributed, sold and/or supplied by Defendants

C.R. Bard and Davol was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing.

22. As a result of having the Product implanted, Plaintiff has experienced significant mental and physical pain and suffering periodically over the years since her 2014 operation.
23. Plaintiff's mental and physical pain became much worse in 2018 and reached a pain level of 9-10/10, causing her to return to Dr. Sartori, who performed the 2014 operation, in March of 2018.
24. Dr. Sartori diagnosed the Product as the cause of the pain.
25. Plaintiff received a second opinion with Dr. Valerie Dunn at Rochester General Hospital and the diagnosis was confirmed.
26. Plaintiff is presently scheduled for surgery to remove and replace the Product.
27. Plaintiff has sustained injuries, has suffered financial or economic loss, including medical expenses and lost income, other damages.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

28. Plaintiff hereby incorporates all above paragraphs by reference as if fully set forth herein.
29. Defendants C.R. Bard and Davol had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling their Product.

30. Defendants C.R. Bard and Davol breached its duty to its customers, including Plaintiff, by failing to design, manufacture, market, label, package, and/or sell its Product in such a manner as the exercise of reasonable care would dictate.
31. Defendants C.R. Bard and Davol negligently failed to warn or instruct the Plaintiff and/or her health care providers of the full extent of the risks and hazards known to exist with use of the mesh in a manner commensurate with the exercise of reasonable care.
32. As a direct and proximate result of the negligence of Defendants C.R. Bard and Davol, Plaintiff has experienced significant physical injury, mental and physical pain and suffering, permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages, loss of earning capacity, loss of earnings, pain and suffering, and other consequential damages.

COUNT II: STRICT LIABILITY - DESIGN DEFECT

33. Plaintiff hereby incorporates all above paragraphs by reference as if fully set forth herein.
34. The Product implanted in Plaintiff was not reasonably safe for its intended uses and was designed in a defective manner so as to be hazardous and harmful to the human body.
35. As a direct and proximate result of the mesh's defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo

future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

36. Defendants C.R. Bard and Davol are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

COUNT III: STRICT LIABILITY - MANUFACTURING DEFECT

37. Plaintiff hereby incorporates all above paragraphs by reference as if fully set forth herein.
38. The Product implanted in Plaintiff was not reasonably safe for its intended use and was manufactured defectively due to having deviated materially from the design specifications of Defendants C.R. Bard and Davol.
39. The deviations from design specifications resulted in defective manufacturing which posed unreasonable risks of serious bodily harm to customers, including the Plaintiff.
40. As a direct and proximate result of the aforementioned defects, Plaintiff has experienced mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.
41. Defendants C.R. Bard and Davol are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT IV: STRICT LIABILITY - FAILURE TO WARN

42. Plaintiff hereby incorporates by reference all above paragraphs as if fully set forth herein.
43. The Product was not reasonably safe for its intended uses and was defective due to its lack of appropriate and necessary warnings. Specifically, Defendants C.R. Bard and Davol did not provide sufficient or adequate warnings regarding, among other things, the serious risk of bodily harm posed by the incompatibility of the material used to make the mesh and human blood and tissue, or the serious risk of infection or serious scarring.
44. As a direct and proximate result of the Product's defects, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.
45. Defendants C.R. Bard and Davol are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective Product.

COUNT V: BREACH OF EXPRESS WARRANTY

46. Plaintiff hereby incorporates all above paragraphs by reference as if fully set forth herein.

47. Defendants C.R. Bard and Davol made assurances as described herein to the general public, hospitals and health care professionals that the Product was safe and reasonably fit for its intended purposes.
48. The Plaintiff and/or her healthcare provider chose the Product based upon the warranties and representations of Defendants C.R. Bard and Davol regarding the safety and fitness of its product.
49. The Plaintiff, individually and/or by and through her healthcare providers, reasonably relied upon the express warranties and guarantees of Defendants C.R. Bard and Davol that the Product was safe, merchantable, and reasonably fit for its intended purposes.
50. Defendants C.R. Bard and Davol breached these express warranties because the Product was unreasonably dangerous and defective as described herein and not as Defendants C.R. Bard and Davol had represented.
51. Defendants C.R. Band's and Davol's breach of its express warranties resulted in the implantation of an unreasonably dangerous and defective product.
52. As a direct and proximate result of Defendant C.R. Band's and Davol's breach of the aforementioned express warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

53. Plaintiff hereby incorporates by reference all the above paragraphs as if fully set forth herein.
54. Defendants C.R. Bard and Davol impliedly warranted that the subject mesh was merchantable and was fit for the ordinary purposes for which it was intended.
55. When the mesh was implanted in the Plaintiff to treat a hernia, the product was being used for the ordinary purpose for which it was intended.
56. Plaintiff, individually and/or by and through her providers, relied upon the implied warranties of merchantability of Defendants C.R. Bard and Davol in consenting to have the subject mesh implanted.
57. The Defendants C.R. Bard and Davol breached these implied warranties of merchantability because the Product implanted in Plaintiff was neither merchantable nor suited for their intended uses as warranted.
58. Defendants C.R. Bard's and Davol's breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product which placed Plaintiff's health and safety in jeopardy.
59. As a direct and proximate result of Defendants C.R. Bard's and Davol's breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff Candace Johnson demands judgment for damages, including punitive, from Defendants C.R. Bard and Davol for an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00) together with interest and costs.

REQUEST FOR JURY TRIAL

The Plaintiff herein request trial by jury of all issues triable by right.

DATED: September 21, 2018

THE SULTZER LAW GROUP P.C.

Adam R. Gonnelli, /s/

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